

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

DATE MAILED: 07/05/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,780	11/19/1999	DANIEL JOSEPH O'MAHONY	99.1063.US	7713
75	90 07/05/2002			
KIRSTEN A ANDERSON ELAN PHARMACEUTICAL RESEARCH CORPORATION 1300 GOULD DRIVE			EXAMINER	
			SCHEINER, LAURIE A	
GAINESVILLE, GA 30504			ART UNIT	PAPER NUMBER
			1648	10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/443,780

Applicant(s)

O'Mahony et al.

Examiner

Laurie Scheiner

Art Unit 1648



The MAILING DATE of this communication appears on the cover sheet with the correspondence address					
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.					
<ul> <li>If the period for reply specified above is less than thirty (30) days, a reply wi</li> <li>If NO period for reply is specified above, the maximum statutory period will a</li> <li>Failure to reply within the set or extended period for reply will, by statute, ca</li> <li>Any reply received by the Office later than three months after the mailing day</li> </ul>	apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Buse the application to become ABANDONED (35 U.S.C. § 133).				
earned patent term adjustment. See 37 CFR 1.704(b).					
Status  1)   Responsive to communication(s) filed on Aug €	2.2004				
	3, 2001				
	s action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.					
Disposition of Claims					
4) 💢 Claim(s) <u>1-8</u>	is/are pending in the application.				
4a) Of the above, claim(s) 4-8	is/are withdrawn from consideration.				
5)  Claim(s)	is/are allowed.				
6) 💢 Claim(s) <u>1 and 2</u>	is/are rejected.				
7)  Claim(s)	is/are objected to.				
8) Claims	are subject to restriction and/or election requirement.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10) The drawing(s) filed on <i>Nov 19, 1999</i> is	s/are a) $\square$ accepted or b) $\square$ objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
	is: a) $\square$ approved b) $\square$ disapproved by the Examiner.				
If approved, corrected drawings are required in re					
12) $\square$ The oath or declaration is objected to by the Ex	caminer.				
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) □ All b) □ Some* c) □ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priori application from the International B	ty documents have been received in this National Stage Bureau (PCT Rule 17 2(a)).				
*See the attached detailed Office action for a list of	of the certified copies not received.				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
a) The translation of the foreign language provisional application has been received.					
15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)					

Art Unit: 1648

Claims 1-8 are pending in this application. Applicant's election of Group I (claims 1-3), as well as specie Zelan033 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Acronyms and abbreviations should be written out or defined in the first claim in which they appear. Therefore, "GIT" as recited in claim 1 should be rewritten as "gastro-intestinal tract (GIT)".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lobie et al. (JOURNAL OF ENDOCRINOLOGY, (1993 Dec.) 139 (2) 371-82).

Lobie et al. clearly teach a monoclonal antibody against a GIT transport receptor. Please see throughout the disclosure for Mab 218 which was generated against the rabbit mammary gland prolactin receptor. Mab 218 was used to study the distribution of the prolactin receptor in

Application/Control Number: 09/443,780

Art Unit: 1648

the rabbit gastrointestinal tract (GIT). In the GIT, the most intense immunoreactivity was associated with the oesophageal epithelium, chief (zymogenic) cells of the fundic mucosa, pancreatic islets of Langerhans and surface epithelial cells of the duodenum and jejunum.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lobie et al. (ENDOCRINOLOGY, (1990) 126 (1), 299-306).

Lobie et al. clearly teach the use of immunohistochemistry to define the cellular distribution of GH receptors in the gastrointestinal tract (GIT) and its derivatives.

Immunohistochemistry was performed in the adult rat GIT with a panel of characterized monoclonal antibodies to the GH receptor. The most intense and heterogenous immunoreactivity was observed in epithelial cell subpopulations of GIT mucosa.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

Application/Control Number: 09/443,780

Art Unit: 1648

Laurie Scheiner/LAS June 24, 2002

> LAURIE SCHEINER PRIMARY EXAMINER

Page 4